REMARKS

The above-identified Application has been carefully reviewed with the Office Action of January 7, 2009, the Examiner's comments, and the art references cited therein in mind. In response thereto, Applicants submit the following arguments in support of patentability. Favorable reconsideration is hereby respectfully requested.

Claims 1-6, 13-83 are rejected under 35 U.S.C. § 102(e) as being anticipated by Dai et al. 35 U.S.C. § 102(e) states:

> A person shall be entitled to a patent unless...(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designed the United States and was published under Article 21(2) of such treaty in the English language.

Applicants respectfully traverse and will prove that the Dai et al reference does not describe the Applicants' invention and, in fact, describes something completely different.

Initially, Applicants offer the following discussion of the present disclosure, accompanied by several examples submitted herewith as Exhibits D-F, to aid in understanding the detailed response to the Office Action presented herein.

In Application US 2005/0134799, Thompson, et. al. teach the measurement of the neuro-ocular wavefront error with a suitable visual aberrometer [0008] and how to correlate the neuro-ocular wavefront error measurements to one or more visual parameters of a subject. The Applicants' invention is a novel method to measure and to correct visual disorders that resolves deficiencies of prior art methods, including the method taught by the Dai et al reference cited by the Examiner.

The neuro-ocular wavefront is a subjective psycho-physical measurement of the wavefront error of the eye-brain visual system of a conscious patient that is spatially-resolved to small regions of the pupil [0045, 0121]. **By measuring the angle that must be imparted to one beam of light to bring its perceived image into co - incidence with that of a second reference beam, the neuro-ocular wavefront error is determined over the sub-pupillary locale where it was tested.** The neuro-ocular wavefront error across the entire pupil can be

constructed from a multiplicity of measurements in the methods taught by the Applicants [0067-0085].

The Applicants' invention utilizes measurements that are based upon subjective alignment of *perceived* images after a beam of light passing through a sub-pupillary locale has stimulated the retina to send nerve impulses to the brain and after these impulses have been processed by the higher order visual pathways and perceived as an image by a conscious patient. Therefore, the neuro-ocular wavefront error contains information about the location within the retina that the patient prefers to focus images and about the neural-transfer function of the higher visual pathways that is spatially resolved to numerous sub-pupillary locales. This unique capability enables the Applicants' invention to measure and to correct anomalies such as ***retinal tilt*** and ***anomalous retinal correspondence***, a processing error that occurs in the higher visual pathways. Prior art methods, including the Dai et al reference, are incapable of detecting these anomalies that exist in the eye-brain systems of conscious patients.

In this Application, the Applicants teach a means to correlate the neuro-ocular wavefront error measurements to parameters that are related to the visual system of a subject, including optical parameters, subject parameters, and environmental parameters [0136] [0137] in order to improve the accuracy of the measurement and corrective treatments that are derived from the measurements.

To explain to the Examiner why the Applicants' invention is patentably distinct from the Dai et al reference, three examples of the eye-brain systems of conscious patients viewing a distant star have been created for the case of a patient with a "perfect" eye-brain system (Patient 1, Exhibit D, Figure 1) and for the case in which the image of the star is blurred by a tilt in the retina and by processing anomalies in the visual pathways of the brain (Patient 2, Exhibit E, Figure 2). A third example, (Exhibit F), is provided to show how the Applicants' invention can measure and correct the vision disorders depicted in example 2. These examples provide a basis for the Applicants' response to specific issues raised in the January 7, 2009 Office Action.

EXAMPLES

EXAMPLE 1: Exhibit D, Figure 1, a "perfect" eye-brain system views a star. Figure 1 shows that light waves from a star diverge through space such that the wavefronts striking the distant eye are essentially parallel. Because light propagates in a direction that is perpendicular to the wavefronts, the light from the star can also be represented as individual rays. In Figure 1,

three rays of light from the star, each 1 mm in diameter, and located in the vertical plane of the eye, are shown and labeled as Rays A, B, and C. Ray A passes through the upper edge of the pupil, Ray B passes through the center of the pupil, and Ray C passes through the lower edge of the pupil. These light rays pass through the Cornea (C) where they are converged to pass through the pupil (P), the round opening in the iris (I), where they are focused further by the crystalline lens (CL) and then focused onto the photoreceptor layer (PL) of the retina. When a conscious patient views the star, its image falls on the region of the retina that provides the highest resolution of vision known as the foveola (FV), shown in enlarged side view in **Figure 1, Inset A**, and in enlarged plan view in **Figure 1, Inset B**.

It is known to those skilled in the art that the ray of light that passes from the target through the center of the pupil to the retina is known as the "Chief Ray" and that the Chief Ray denotes the "visual axis of the eye" which, in this example, is identical to Ray B. It is also known to those skilled in the art that Rays A and C are known as "limiting Rays" because they pass at or near the edge of the aperture and thus determine the maximum diameter of the image (or image blur) that is focused on the retina. In this example, Rays A and C determine the maximum diameter of the image in the vertical meridian of the retina **(Figure 1, Inset B)**. Note that in **Figure 1, Inset A**, that in this "perfect eye," the photoreceptor layer in the foveola is exactly perpendicular to Ray B, the Chief Ray, and to the Visual Axis of the Eye. When the photoreceptor layer is perpendicular to the Chief Ray this orientation provides optimal imaging of objects onto the retina with minimum distortion compared to a condition in which the retina is tilted relative to the Chief Ray, as will be discussed further below.

The photoreceptors in the foveola at points 1, 2, and 3 are stimulated by Rays A, B, and C, respectively, as shown in a side view **Figure 1, Inset A,** and in a frontal view **Figure 1, Inset B** of the foveola. Note that Rays A and C pass near the edges of the pupil and they are focused on photoreceptor points 1 and 3. Because, as noted previously, this "perfect eye" is free from refractive error or aberrations, the distance between the image formed by limiting Ray A and the Chief Ray B and the distance between the image formed by limiting Ray C and Chief Ray B is determined by the effects of diffraction caused by the edges of the pupillary aperture that Rays A and C pass near to. It is known to those skilled in the art that such a "perfect" eye would be "diffraction limited," meaning that the size of the image of a point source of light, such as a star, would be a minimum size that is limited only by the blurring effects of diffraction. This diffraction-limited diameter is shown in **Figure 1, Inset B** as a radius (DL) around the center of the foveola, point 2.

After they are struck by light from the star, the photoreceptors in the foveola (FV) generate nerve impulses (NI) that are conducted through the optic nerve, (ON) to the patient's brain (BR), where additional conduction and processing (sinusoidal arrows) occurs successively through the higher order visual pathways that are located in the lateral geniculate body (LG), optical radiation (OR), occipital cortex (OC), and frontal cortex (FC) of the brain. As a result of the conduction and processing of neural impulses in the higher order visual pathways, the conscious patient perceives the image of the star in perceived image space (PIS) which is represented by **Figure 1, Inset C**. The portions of the image of the star that is formed by Rays A, B, and C by impinging on photoreceptor layer (PL) spots 1,2,and 3, respectively, are shown as orange dots labeled 1', 2', and 3', respectively in **Figure 1, Inset C**. Note that in this "perfect" eye-brain system, retinal spots 1,2, and 3 are aligned in the vertical meridian of the retina and that they correspond to perceived images 1', 2', and 3'that are also aligned perfectly in the vertical meridian of the patient's perceived image space (PIS) as shown in **Figure 1, Inset C.** This exact spatial matching of object space (rays from the star) to perceived image space (PIS) is known to those skilled in the art as "normal retinal correspondence." Stated another way, normal retina correspondence means that the light rays of the object, when focused upon the retina, produce perceived images that are spatially-matched to their corresponding locations in object space.

EXAMPLE 2: Exhibit E, Figure 2, an eye-brain system with a tilted retina and with anomalous retinal correspondence (ARC). In Figure 2, a similar diagram has been created for Patient 2 with an emmetropic right eye that has a photoreceptor layer (PL) in the foveola (FV) that is not perpendicular to the visual axis of the eye (Ray B) and that possesses processing anomalies in his visual pathways that causes anomalous retinal correspondence at retinal Spot 6. Each anomaly of this eye-brain system will be discussed in more detail below.

In the eye brain system of Patient 2 shown in **Figure 2**, light emanates from the star and it is focused by the eye in the exact manner as discussed in the Example 1. However, as seen in **Figure 2, Inset A,** the photoreceptor layer PL is not perpendicular to the visual axis of the eye (Ray B). Instead, the photoreceptor layer (PL) is "tilted" by angle ϴ (**Figure 2, Inset A**) such that the upper portion of PL creates an acute angle with the visual axis (Ray B), and the lower portion of PL creates an obtuse angle with the visual axis (Ray B). As a consequence of this tilt, Rays A and C are focused at spots 4 and 6 respectively, and the distance between retinal spots 4 and 5 (**Figure 2, Inset A and B**) is greater than the corresponding distance between retinal

spots 1 and 2 in Patient 1 (**Figure 1, Inset A and B**) and the distance between retinal spots 5 and 6 in Patient 2 (**Figure 2, Inset A and B**) is also greater than the corresponding distance between retinal spots 2 and 3 in Patient 1 (**Figure 1, Inset A and B**). As seen in **Figure 2, Inset B**, the distance between the Chief Ray and the Limiting Rays is approximately twice as great in Patient 2 as the diffraction-limited distance DL in Patient 1.

Following processing by the higher order visual pathways in the brain (BR), the perceived image of the star, depicted by **Figure 2, Inset C** appears to Patient 2 to be more blurred, more diffuse, and more irregular than the image of the star that is perceived by Patient 1 with the "perfect eye-brain system." This difference is apparent by comparing the image of the star in perceived image space (PIS) between Patient 1 (**Figure 1, Inset C)** compared to the image of the star perceived by Patient 2 (**Figure 2, Inset C)**. The degradation of the perceived image in Patient 2 is a consequence of the tilt of the photoreceptor laser PL in Patient 2's eye. Retinal tilt is a type of neuro-ocular wavefront error that is related to the position of the retina, and the location on the retina that the patient prefers to have the image focused.

Referring now to **Figure 2, Inset C**, note that the portion of the perceived image that results from Ray C that falls on PL location 6 and is shown as 6' in **Figure 2, Inset C** is not in the vertical midline of the perceived image space (PIS) in Patient 2, but that it is displaced to the right by a distance that is denoted ΔR. 6' is located to the right of its expected location despite the fact that Ray C fell on spot 6 which is in the vertical midline of the photoreceptor layer PL as shown in **Figure 2, Inset B**. Therefore, it is evident that although Ray C struck the retina in the vertical meridian, the corresponding perceived image 6' that resulted from Ray C is NOT in the vertical meridian of Patient 2's perceived image space (PIS), but rather, some distance ΔR to the right. Such an anomaly is known to those skilled in the art as "anomalous retinal correspondence" or "ARC" and it is caused by processing anomalies in the higher visual pathways and not by any abnormality of the optics of the eye or in the retina.

In the eye-brain system of Patient 2, neuro-ocular wavefront errors are present as defined by the Applicants in [0008]. Neuro-ocular wavefront errors are distinct from ocular wavefront errors, because they may be caused by anomalies in retinal position, such as tilt of the photoreceptor layer, and/or they may be caused by processing anomalies of the higher order visual pathways such as ARC.

EXAMPLE 3: Exhibit F, Figure 3, neuro-ocular wavefront errors of the eye-brain system of Patient 2 is measured using the method taught in the Applicants' application.

Figure 3 illustrates how the neuro-ocular wavefront error of the patient in example 2 is measured using the methods described by the Applicants. As discussed in the Applicants' invention in [0050-0097], the patient views images produced by two beams of light, one beam contains a reference target such as a reticle with crosshairs, and a second beam contains the image of a spot. By using the same drawing configuration that was used in Figures 1 and 2, Figure 3 shows that the image of the star has been replaced by a suitable visual aberrometer, such as the examples cited by the Applicants in [0008] in their application. In Figure 3, Ray B, the Chief Ray passing through the center of the pupil now contains the image of a reticle (RET) with a crosshair and will serve as the "reference beam." Rays A and C from the visual aberrometer will contains the image of a test spot. Ray A passes through the cornea(C) and crystalline lens (CL) where it is focused upon the photoreceptor layer (PL) of the retina at the spot labeled 7A. After processing by the visual pathways, this spot is perceived by the patient as 7A' in his perceived image space (PIS) as shown in **Figure 3, Inset C**. By interactively moving a joystick or similar device as taught by the Applicants in [0050-0097] of their Application, the patient changes the angle at which Ray A impacts the cornea by some angle α without changing its position on the cornea. The new position of Ray A is denoted as Ray A' in Figure 3. By changing the angle α of Ray A, the patient moves the position on the retina from 7A to 7B **(Figure 3, Insert B)** and the perceived spot in (PIS) moves from position 7A' to position 7B' in perceived image space (PIS) as shown in **Figure 3, Inset C.**

Once this task is complete and the angle α has been recorded, the test beam is now moved to the position shown by Ray C which falls on point 9A in photoreceptor layer PL as shown in **Figure 3, Inset A and B**, generating spot 9A' in the perceived image space (PIS) of patient 2 as shown in **Figure 3, Inset C**. Again, the patient interactively moves the joystick to impart angles α and β to Ray C moving it to a new position shown as Ray C'. This action moves the retinal image from 9A to 9B on photoreceptor PL and the perceived image in PIS is moved from 9A' to 9B' at which time angles α and β are recorded. Note that α is in the vertical plane of the eye, and β is in the horizontal plane of the eye, orthogonal to angle α.

By measuring a plurality of spots across the pupil, the neuro-ocular wavefront error of Patient 2 can be measured. Once this information is known, a corrective modality such as glasses, contact lenses, or laser surgery treatment can be designed as taught by the methods in the Applicants' invention.

It is thereby seen in these examples that the neuro-ocular wavefront data and the neuro-ocular wavefront measurement obtained by the methods taught by the Applicants account for, and can correct for, the blur that is caused by the position of the retina such as retinal tilt. It is also shown that the Applicants' method accounts for processing anomalies, such as anomalous retinal correspondence, that exist in the higher order visual pathways. With this explanation of the Applicants' invention now in mind, a detailed response to the Examiner's January 7, 2009 Office Action will be provided.

The January 7, 2009 Office Action, beginning with paragraph 3 is reproduced below in its entirety:

> 3. Claims 1-6, 13-83 are rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al (US 2008/0106698). Regarding claims 13-14 and 50-73, Dai et al, Figs. 3, 9C-13, 18C-24, discloses a device for establishing an optical surface shape ([f]or presbyopia correction) *based on the residual accommodation range and pupil size range of the patient* when the patient *gazes* at different viewing conditions (see paragraphs [0015], [0070], [0141], [0142], [0148], [0231] and [0232]). The residual accommodation range and pupil size range convert into the optical surface shape by using the goal function including the Zernike polynomials. As understood in the art that the residual accommodation range is nothing more than an aberration error and/or wavefront errors and/or wavefront data. Thus, Dai et al's teachings of gazing at different viewing conditions in measuring the pupil sizes, the residual accommodation range provides an effects of the neurological pathways between the eye and the brain. Thus the Dai et al's teachings of the effects of the neurological pathways between the eye and the brain and the wavefront error and/or wavefront data are within the meaning of neuro-ocular wavefront data as the Applicants clearly defined in the response dated February 15, 2008.
>
> Further, the Dai et al's device including a module and/or an optimizer for establishing the presbyopia correction via a Goal function including Zernike polynomials being expressed in term of an equation including coefficients a, b, c, d, e, and f (see page 8 [0097]). These coefficients in combine with the input patient parameters are nothing more than correlating means as the Applicants claim.
>
> Establish an optical surface shape is nothing more than "obtain neuro-ocular wavefront data" as the Applicants claim. Further Dai et al (page 5, [0070]) discloses that "the present invention will often take advantage of the fact that the eye changes in viewing distance". It is clear that obtain the neuro-ocular wavefront data via MTF in combine with the interactivity of patient via "the fact that the eye changes in viewing distance". In another word, Dai et al discloses interactively obtaining means.
>
> In response to the previous rejections, the Applicants argue that "Dai et al does not teach or suggest "obtaining neuro-ocular wavefront data"" and concludes "Applicants respectfully submit that independent claim 13 is allowable for at least the reason that Dai et al fails to disclose, teach, or suggest at least the features recited and emphasized above in claim 13". However the Applicants do not demonstrate how his broadly claimed

invention patentably distinct from the Dai et al reference. Although Dai et al does not mention the word "neuro-ocular", the Applicants neither demonstrate the reasons why the Dai et al's wavefront error or wavefront data cannot be a "neuro-ocular" wavefront data, nor indicate Dai et al's neuro-ocular wavefront data being a "raw" unmodified neuro-ocular wavefront data, nor analyze the Dai et al's gazing the different viewing conditions cannot provide the effects of the neurological pathways between the eye and the brain in obtaining the wavefront data as the Applicants' defined in the response dated February 15, 2008. In another words, the Applicants do not point out the patentable feature in his broadly claimed invention distinct from the Dai et al's reference.

In fact, Dai et al discloses a neuro-ocular wavefront data as discussed above and the gazing at different viewing conditions in measuring the pupil sizes, the residual accommodation range provides an effects of the neurological pathways between the eye and the brain as the same as the Applicants'. It is agreed that the Dai et al does not pupil sampling maps/matrix in a refractometer adapted to acquire neuro-ocular wavefront data. However the Applicants do not prove that pupil-sampling maps is only way to acquire neuro-ocular wavefront data. A neuro-ocular wavefront data can be obtained without pupil-sampling maps as disclosed by Dai et al as discussed above. In another words, the broadly claimed invention is disclosed by Dai et al under35 USC 102.

Regarding claims 13, 59, since the optical surface shape is calculated from the coefficients in combine with the input patient parameters, the Dai et al programmable device including means for calculating the correction factors for treating the patient.

Regarding claims 60-63, Dai et al ([0023], [0093]) discloses the correction factors is used to treat the patient with a contact lens, a spectacle lens or a tissue ablation profile for refractive surgery. The refractive surgical techniques such as PRK, LASIK, LASEK. (See para [0068].)

Regarding the method claims 1-6 and 17-49, it should be noted that although claims 1-6 and 17-49 "method claims", the method steps consist of the broad steps of "obtaining" and "correlating" etc and therefore these steps would be inherently satisfied by the apparatus of the Dai et al reference.

Regarding claims 15 -16 and 74-73, since Dai et al's invention including a module and/or optimizer and/or a programmable device wherein the programmable device for obtaining neuro-ocular data and correlating the neuron-ocular to the patient parameter. The programmable device including instruction in establishing the presbyopia correction. The programmable device inherently includes computer-readable code medium for optimizing the presbyopia correction. Thus the Dai et al's computer-readable code medium including computer-readable code adapted to instruct a programmable device to interactively obtain neuro-ocular wavefront data from a subject, and computer-readable code adapted to instruct a programmable device to correlate the neuro-ocular wavefront data to parameters associated with the visual system of the subject.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huy Mai whose telephone number is (571) 272-2334. The examiner can normally be reached on M-F (8:00 a.m.-4:30 p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ricky L. Mack can be reached on (571) 272-2333. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1562.
lHuyMai/

RESPONSE TO OFFICE ACTION

Based upon their understanding of the Examiner's January 7, 2009 Office Action that rejected claims 1-6 and 13-83 as being anticipated by Dai et al, the Applicants have grouped the Examiner's findings into four categories which are listed below and briefly summarized:

1. Measurement of the accommodative range (taught by Dai et al) is equivalent to measurement of the neuro-ocular wavefront error (taught by Applicants). The Examiner finds that the Dai et al reference teaches the creation of a corrective shape that is based upon residual accommodative range. The Examiner believes that "residual accommodative range" is equivalent to "wavefront error" as understood in the art. Therefore, the Examiner has concluded that the Dai et al invention teaches creation of a corrective shape that is equivalent to the method of using the neuro-ocular wavefront error that is taught by the Applicants.

2. The teachings of the Dai et al reference and teachings of the Applicants concerning the effects of the neurological pathways on the corrective shape are equivalent. The Examiner asserts that the Dai et al method teaches a means of determining the effect of the neurological pathways for a correction that is equivalent to the method of incorporating the effects of the neurological pathways that is taught by the Applicants.

3. The teachings of the Dai et al reference and the teachings of the Applicants concerning interactive testing means are equivalent. The Examiner finds that that the

interactive means taught by the Dai et al reference and the interactive means taught by the Applicants are equivalent.

4. The Applicants has not proven that his invention is patentability distinct from Dai et al. The Examiner finds that the Applicants have failed to prove why the Applicants' invention is patentably distinct from the invention that is disclosed in the Dai et al reference. The Examiner questions why the Dai et al invention cannot measure the neuro-ocular wavefront as described by the Applicants.

These four findings are analyzed in light of the examples provided in Figures 1-3 cited above, Exhibits D-F, and formal definitions provided by authoritative textbooks, and other references that are attached as EXHIBITS A-C.

Applicants' Response to Examiner's Objections

Finding 1	**Text from Office Action**
Residual accommodative range [as taught in Dai] is equivalent to neuro-ocular wavefront aberration [as taught by Applicants]	"As understood in the art that the residual accommodation range is nothing more than an aberration error and/or wavefront errors and/or wavefront data

RESPONSE TO FINDING 1:

The textbook Duane's Ophthalmology, Volume 1, Chapter 33, pp 50-51, attached herein as EXHIBIT A, defines **residual accommodative range** as the distance between the near point and the far point of the eye that has not been lost due to the effects of aging (Exhibit A, Figure 33-69, reproduced below).

> The corresponding distance between the near point to the far point of p - r = a in meters is termed the range of accommodation (Fig 33-69).

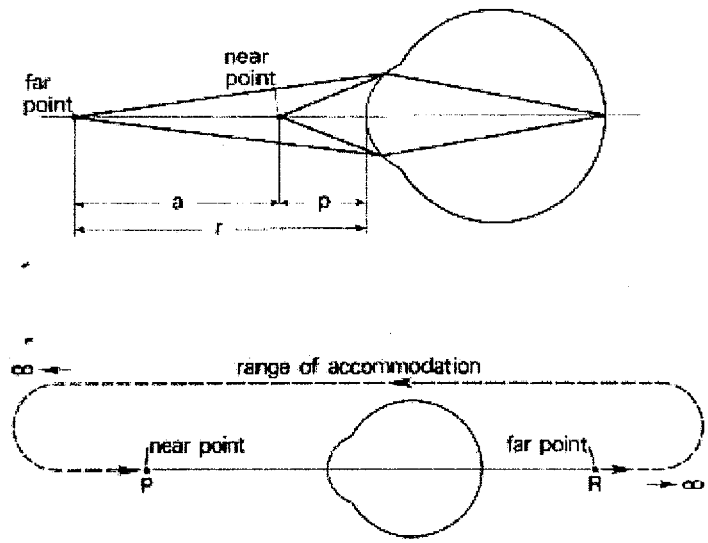

Fig 33-69. Range of accommodation in myopia (top) and hyperopia.

Chapter 5, Page 52 of the textbook <u>Customized Corneal Ablation – The Quest for SuperVision</u> is attached as EXHIBIT B. This textbook defines *Aberration error and/or wavefront error* as the difference between the shape of a wavefront of light that has been aberrated by all of the elements in the eye's optical system and the shape of a perfect, nonaberrated wavefront, which is usually represented as a flat surface in the plane of the pupil. The optical elements of the eye that impart aberrations include the anterior and posterior surfaces of the cornea and the crystalline lens as shown in figures 5-2 and 5-3, reproduced below:

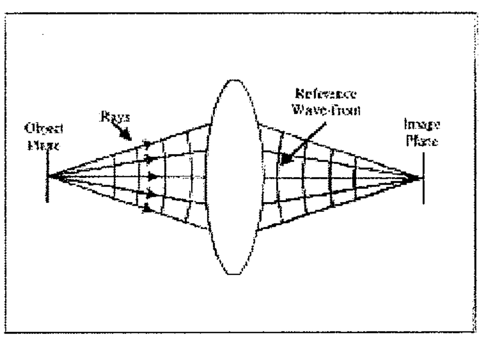

Figure 5-2. An ideal optical system. Light from the object plane is focused by the lens and converges at the image plane. Deviation from the ideal wavefront defines aberration.

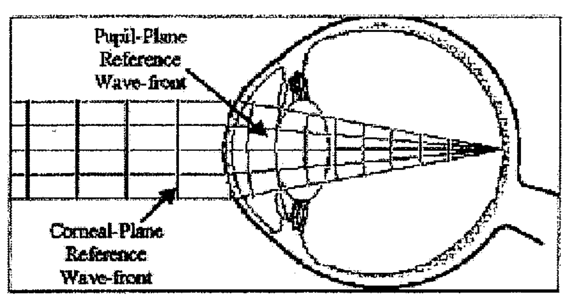

Figure 5-3. An ideal eye. Deviation from the ideal wavefront defines aberration.

Collecting **<u>neuro-ocular wavefront data</u>** is described by the Applicants in [0059] as a method in which "the subject is requested to interactively move the test spot to the center of the

alignment target (Figure 1, of the application, reproduced below). This process is repeated for each of the sampling points in the sampling map. The <u>obtaining</u> of all alignment data, in effect, represents the interactive acquisition of the neuro-ocular wavefront data. Once the data has been collected from all of the sampling points, it is <u>correlated</u> and the collected data can be used to reconstruct the neuro-ocular wavefront as described by the Applicants in [0060-0092] and is measured through a testing process "that assesses multiple points within the pupil. This same process has been demonstrated again graphically in Figure 3 of the application.

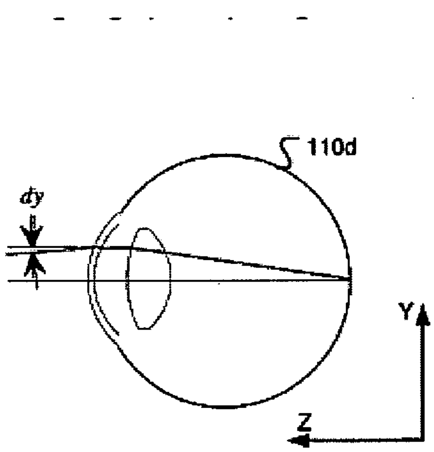

Fig. 1

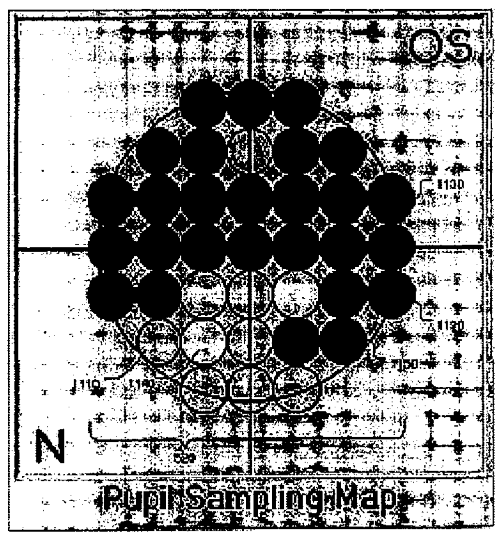

Fig. 3

Thus, the Applicants' invention teaches how to obtain neuro-ocular wavefront data and how to correlate the neuro-ocular wavefront error as steps in their invention.

The Examiner notes that the Dai et al reference teaches the determination of the residual accommodative range and states in the Office Action that this is an equivalent measurement.

The distance between the near point and the far point of the eye (accommodative range) is a function of the refractive error of the eye and the residual accommodative amplitude of the eye that has not been lost to aging. The neuro-ocular wavefront error, as defined by the Applicants, is a measurement of the wavefront error of the eye-brain system that is made by a conscious patient performing an interactive alignment task that is spatially resolved across multiple pupillary locales.

Therefore, the "**<u>residual accommodative range</u>**" and the "**<u>neuro-ocular wavefront error</u>**," as defined by the references cited above are distinct measurements of two entirely

different characteristics of the visual system. The terms do not mean the same thing, they are not interchangeable, nor can one measurement be derived, or inferred, from the other.

In the context in which they are used, it is no more possible to substitute "residual accommodation range" for "neuro-ocular wavefront error" than it is possible to substitute a measurement of a patient's blood pressure with that of the patient's pulse when describing an invention to monitor heart performance. While both measurements are ***related*** to the cardiovascular system, each measurement refers to a distinct aspect of the system's performance.

Because **residual accommodative range** used in the Dai et al method and the **neuro-ocular wavefront error** are not equivalent measurements, the Examiner's anticipation finding that is based upon this assumption is therefore disproven. The Office has thus provided no evidence that the Applicants' claims are not patentable. Contrary to the position taken by the Office, the Applicants demonstrate how the claims are patentably distinct from the Dai et al reference. They also demonstrate a different metric is being measured. They also demonstrate that Dai et al's data is not obtained or correlated as in the Applicants. For a proper rejection of a claim under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features of the claim at issue. *See, e.g., E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988).

Finding 2	Text from Office Action
The teachings of the Applicants and the teachings of Dai concerning the effects of the neurological pathways are equivalent	"Thus, Dai et al's teachings of gazing at different viewing conditions in measuring the pupil sizes, the residual accommodation range provides an effects of the neurological pathways between the eye and the brain. Thus the Dai et al's teachings of the effects of the neurological pathways between the eye and the brain and the wavefront error and/or wavefront data are within the meaning of neuro-ocular wavefront data as the applicant clearly defined in the response dated February 15, 2008."

RESPONSE TO FINDING 2:

Here, the Examiner asserts that the method taught in the Dai et al reference of measuring differences in accommodative power of the lens and the size of the pupil that occur

when the patient changes his gaze between objects located at different distances provides "an effect of the neurological pathways between the eye and the brain as taught by the applicant." For this finding to be valid, the effects of the neurological pathways taught in the methods of the Dai et al reference must be equivalent to the effects of the neurological pathways taught by methods in the Applicants' invention.

However, the methods taught in the Dai et al reference teach different effects of the neurological pathways than the methods that are taught by the Applicants' invention. The neural pathways that cause the effects in the Dai et al method and the Applicants' method differ in location and in function. Therefore teachings of the effects of the neurological pathways in the two methods are not equivalent and they are not interchangeable.

Different effects. In the method taught by Dai et al, a patient changes his gaze from a distant object to a near object at a second distance in order to trigger the accommodative reflex of the eye. Changes in the power of the crystalline lens (measured in spherical power)and changes in pupil diameter (measured in mm.) are recorded. Thus, the **effects of the neurological pathways** are to control the involuntary muscles in the eye that change the size of the pupil and the power of the lens.

In contrast, **the interactive alignment task taught by the Applicants require the patient to move the perceived image of one beam of light that traverses a small pupillary locale such that it is brought into co-incidence with that of second beam by moving a joystick or similar means to change the angle at which the first beam enters the cornea**. An example of such a measurement has been provided to the Examiner in Exhibit F, Figure 3 above.

Thus, the effects of the neurological pathways in the Applicants' method is the conscious perception of two images, and their subsequent alignment by directing actions of the patient's motor system. Unlike the methods taught in the Dai et al reference, the Applicants do not teach the patient to redirect his gaze between objects located at different distances in order to trigger the accommodative reflex of the eye, nor do they teach recording the size of the pupil, or the amount of accommodative power added by the crystalline lens.

Unlike the methods taught in the Applicants' invention, Dai et al does not teach the performance of an alignment task of aligning two beams of light conducted by a conscious subject that is repeatedly performed through multiple sub-pupillary locales for the purpose of determining the angles necessary to correct an errant beam of light that traverses a discrete sub-pupillary locale.

The changes in spherical power of the lens and the changes in diameter of the pupil that occur during accommodation (Dai et al) are different neurological effects than the conscious perception of two images and their alignment. Therefore, the effects of neurological pathways as used in the two inventions are distinct, they are non-interchangeable, and one effect cannot be derived or inferred from the other.

Different pathways. In addition to employing effects of the neurological pathways that are distinct, the Dai et al reference and the Applicants' invention teach tasks that use completely different neurological pathways during their implementation. As discussed by Duane's Ophthalmology, Chapter 4, pp 1-2, that is appended as APPENDIX C, the pathways involved in conscious visual perception involve:

> "The retina, optic nerves, chiasm, tracts, lateral geniculate nuclei, geniculocalcarine radiations, calcarine cortices, visual associational areas, and related interhemispheral connections comprise the primary visual-sensory system in man."

The anatomical location of these pathways is shown in Figure 4-1 and reproduced below from the Duane's textbook:

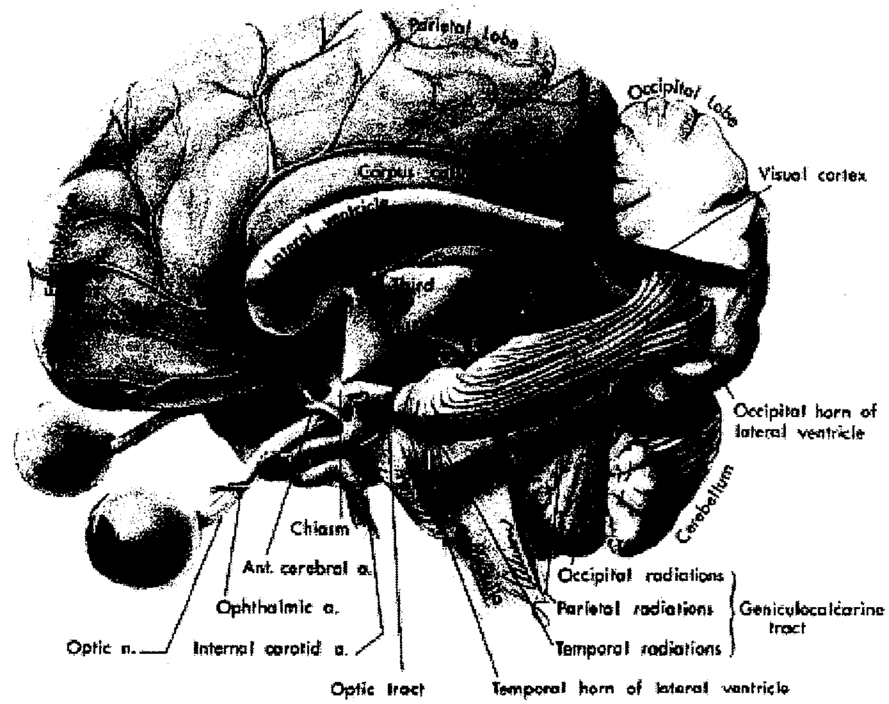

Fig 4-1. The visual-sensory system. The left cerebral hemisphere has been removed with exception of occipital lobe and ventricular system. The left lateral geniculate body is hidden (*arrow*). Note the following relationships: optic nerve with internal carotid and anterior communicating arteries; chiasm in the floor of the third ventricle; forward sweep of temporal radiations around lateral ventricle; course of occipital radiations toward interhemispheral surface of occipital lobe. The cerebral falx and cerebellar tentorium are not illustrated.

The pathways involved in conscious perception of visual images have been shown graphically and labeled LG, OR, OC, and FC in Figures 1-3 above (Exhibits D-F). In contrast, the neural pathways that are operative in the Dai et al method involve the accommodative reflex which uses different neural pathways that are located in the midbrain as discussed by Duane's textbook below:

> **Near Reflex and Accommodation**:
>
> With accommodative effort, caused either by a blurred retinal image or conscious visual fixation on a near object of regard, a "near synkinesis" is evoked, including (1) increased accommodation of the lens, (2) convergence of the visual axes of the eyes, and (3) pupillary constriction...... A midbrain "center" for accommodative vergence is suggested on theoretical grounds but has not yet been anatomically verified. **However, the anteromedian nucleus (Edinger - Westphal) of the oculomotor complex in the rostral midbrain has been mapped stereotactically and may be divided functionally into a rostral portion concerned with accommodation, a caudal portion that elicits**

papillary constriction, and a middle segment that, when stimulated, results in accommodation and constriction. The final pathway for pupil constriction, whether evoked by light or accommodative effort, consists of the oculomotor nerve, ciliary ganglion, and short posterior ciliary nerves.

It is evident to those skilled in the art of neurology and neuro-ophthalmology that the neural pathways involved in the accommodation reflex are distinct in location and function from the pathways that are responsible for visual perception and performance of an alignment task as stated by the Applicants in the present disclosure, in the remarks herein, and as shown graphically in Exhibit F, Figure 3 above.

As shown above, it would not be possible to substitute the method of incorporating the effects of neural pathways as taught by Dai et al – i.e. stimulating the accommodative reflex by changing gaze distance – with the subjective alignment task taught by the Applicants – i.e. performing an interactive alignment task on two beams of light that traverse sub-pupillary locales.

The Dai et al method would fail to provide the changes in angles required to be imparted to a test beam over a small pupillary locale that is necessary to compute the neuro-ocular wavefront. Moreover, if the accommodation reflex was induced by the method of changing gaze between objects at differences as taught by Dai et al during acquisition of neuro-ocular wavefront data as taught by the Applicants, faulty measurement of the neuro-ocular wavefront would occur.

Finding 3.	**Text from Office Action**
Dai and the Applicant teach interactive means that are equivalent.	"It is clear that obtain the neuro-ocular wavefront data via MTF in combine with the interactivity of patient via "the fact that the eye changes in viewing distance". In another word, Dai et al discloses interactively obtaining means."

RESPONSE TO FINDING 3:

While it is true that the method of Dai et al involves an ***interactive task***, that is, gazing at one target, then gazing at another while measurements of pupil size and the addition of accommodative power are made, the interactive task taught by Dai et al is quite distinct from the interactive task taught by the Applicants.

In the interactive task taught by the Applicants' invention, the patient views images that are formed by two light beams that enter the eye through small pupillary locales and the patient moves the perceived image of one beam of light such that it is brought into co-incidence with that of second beam by moving a joystick or similar means to change the angle at which the first beam enters the cornea. The change in angle is recorded, and then another sub-pupillary locale is queried. The Examiner is referred to Exhibit F, Figure 3 and its related description above as an example.

The interactive task taught by Dai et al results in an activation (or deactivation) of the accommodative reflex of the patient's eye. The result is a change in pupil size and a change in the power of the crystalline lens which are used in the determination of the corrective shape as taught by the Dai et al reference.

The interactive task taught by the Applicants do not evoke a change in the accommodative status of the eye, but it results in a measurement of the local neuro-ocular wavefront error of a conscious eye-brain system that is spatially resolved to the pupillary locale where it was measured.

It is not possible to substitute the interactive means taught by Dai et al (accommodative reflex activation) with the interactive means taught by the Applicants (sub-pupillary alignment task of the beams of light) in the Applicants' method. The interactive means taught by Dai et al cannot measure the change in angle required to align the perceived image of the test beam with that created by the reference beam. In addition, a change in the accommodative status of the eye caused by the interactive method of Dai et al would cause erroneous measurement of the neuro-ocular wavefront.

The nature of the tests described by Dai et al and the Applicants are distinctive, non-equivalent, and they cannot be substituted.

Finding 4.	Text from Office Action
The Applicants have not proven their invention is patentability distinct from Dai.	"However the applicant does not demonstrate how his broadly claimed invention patentably distinct from the Dai et al reference. Although Dai et al does not mention the word "neuro-ocular", the applicant neither demonstrate the reasons why the Dai et al's wavefront error or wavefront data cannot be a "neuro-ocular" wavefront data, nor indicate Dai et al's neuro-ocular wavefront data being a "raw" unmodified neuro-ocular wavefront data, nor analyze the Dai et al's gazing the different viewing conditions cannot provide the effects of the neurological pathways between the eye and the brain in obtaining the wavefront data as the applicant's defined in the response dated February 15, 2008. In another words, the applicant does not point out the patentable feature in his broadly claimed invention distinct from the Dai et al's reference.

A proper rejection of a claim under 35 U.S.C. §102 requires that a single prior art reference disclose each element of the claim. *See, e.g., W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference. *See e.g., In re Paulsen,* 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994); *In re Spada*, 911 F.2d 705, 15 USPQ 2d 1655 (Fed. Cir. 1990). As emphasized below, Dai et al do not disclose each element of any of the pending claims.

RESPONSE TO FINDING 4:

As discussed in detail above, the Applicants have now shown the Examiner that their invention is patentably distinct from the Dai et al reference because:

The Neuro-Ocular Wavefront Error is a Distinct Metric from Residual Accommodative Range

- The Dai et al reference teaches a means to create a corrective shape to mitigate presbyopia that is based, in part, upon a measurement of the patient's residual accommodative range; the Applicants' method does not teach the measurement of the

residual accommodative range. The Examiner has been provided with authoritative textbook references that show that the measurement of the neuro-ocular wavefront error is a metric that is distinct from, and not interchangeable with, the residual accommodative range.

- The Applicants' invention teaches how to obtain measurements that are based upon subjective alignment of *perceived* images after a beam of light passing through a sub-pupillary locale has stimulated the retina to send nerve impulses to the brain and after these impulses have been processed by the higher-order visual pathways and perceived as an image by a conscious patient (neuro-ocular wavefront error); the Dai et al reference does not teach alignment of perceived images that traverse sub-pupillary locales. Therefore, the inventions teach the measurement of distinct aspects of the visual system.

The Inventions Incorporate Distinct Interactive Means

- The Dai et al reference teaches a means to create a corrective shape for mitigating presbyopia by measuring the changes in accommodation (power change of the crystalline lens) and the changes in pupil size that occur when a patient evokes the accommodative reflex of the eye; The Applicants' method does not teach the evocation of the accommodative reflex, a change in the power of the crystalline lens, or a change in pupil size.

- To the extent that the Dai et al reference teaches "patient interactivity," it is only in requiring a patient to gaze at different objects at different distances in order to evoke the accommodation reflex of the eye and change the size of the pupil. The Dai et al method of changing gaze change is not taught to be performed through sub-pupillary locales, as the Applicants teach in his invention. Therefore, the inventions teach distinct interactive means.

- Substituting the interactive means taught by Dai et al with the interactive means taught by the Applicants would fail to provide measurements that are required for the Applicants' invention to operate. Furthermore, the changing power of the crystalline lens evoked by the Dai et al method would corrupt measurements of the neuro-ocular wavefront when the methods taught by the Applicants were performed, rendering the results useless.

The Inventions Invoke Distinct Effects of the Neurological Pathways

- The effect of the neural pathways in the methods taught by the Dai et al reference is to change the power of the crystalline lens and the size of the pupil, effects that are governed by the autonomic nervous system located primarily in the mid-brain. The effect of the neural pathways in the method taught by the Applicants is the perception of images and the performance of an alignment task which is accomplished through the higher order visual pathways.

- The Examiner has been provided references from authoritative textbooks that show that the higher order visual pathways utilized in the Applicants' invention are distinct in location and function from the pathways that control accommodation and pupil size that are used in the methods taught in the Dai et al reference.

The Applicants' Invention Can Measure Errors Caused by Retinal Position, Such as Retinal Tilt and Processing Anomalies Such as ARC; The Dai et al Reference Cannot

- The Examiner has been provided with detailed examples above that show that the Applicants' method contains information that permits the measurement of errors that are caused by the position of the retina, such as retinal tilt, and errors caused by anomalies of the neural-transfer function of the higher visual pathways, such as anomalous retinal correspondence (ARC). Because the Dai et al reference does not make any measurement of a perceived image after it has traversed a sub-pupillary locale and been processed by the retina and the higher order pathways, the Dai et al method cannot measure retinal tilt or ARC or design corrections for them.

- In their Application, the Applicants teach a means to correlate the neuro-ocular wavefront error measurements to parameters that are related to the visual system of a subject, including optical parameters, subject parameters, and environmental parameters in order to further improve the accuracy of the measurement and the efficacy of corrective treatments that are derived from the measurements; The Dai et al reference does not teach such methods of correlation based upon subjective alignment of *perceived* images after a beam of light has passed through a sub-pupillary local. Therefore the Dai et al method fails to incorporate the benefits of refining subjectively derived measurements as the Applicants teach.

CONCLUSION

With the Remarks, Exhibits, and references presented herein, it is believed that all the claims remaining in the Application are in condition for allowance. Early and favorable action in this regarding is hereby respectfully requested. Should there be any minor informalities remaining, the Examiner is respectfully requested to call the undersigned attorney so that this case may be passed to issue at an early date.

Respectfully submitted,

James W. Kayden

James W. Kayden; Reg. No.: 31,532

THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.
Suite 1500
600 Galleria Parkway N.W.
Atlanta, Georgia 30339
(770) 933-9500